

REMARKS

Amendment to the claims has been made to overcome the Examiner's objection of claims 23-25 and to further define the invention in claim 32 explicitly in terms of a separate unsleeved ultrasonically vibrated needle for emulsifying a cataract and for aspirating emulsified tissue.

Heretofore, only a sleeved vibrated needles have been utilized in phacoemulsification procedures. Typically phacoemulsification needles have utilized a sleeve in order to either pass irrigation fluid or aspirated fluid thereover in order to cool the needle to prevent irritation of a wound entry. This requires a sleeve! None of the references cited by the Examiner include an unsleeved ultrasonically driven needle utilizing aspiration therethrough for cooling the needle.

The Examiner's rejected claims 3, 4, 26-28 and 31 under 35 USC 103(c) as being unpatentable over U.S. 4,608,050 to Wright, et al. in view of U.S. 6,319,222 to Andrew, et al.

In this rejection the Examiner stated that Wright discloses an apparatus for the removal of lens tissue (Fig. 1) comprising a first instrument 1 and 2 having a shaft 1 used in irrigation. The instrument has a tip capable of manipulating a cataract. The device further comprises a second instrument 6 with the second instrument being a sleeveless aspirator.

The Examiner acknowledges that Wright, et al is silent about the size of the wound aperture required to insert the second instrument, but relies on Andrew for teaching a device used in cataract surgery wherein the surgical device fits within an incision that is about 1 to 2 mm to minimize the damage to the patient and reduce healing time.

The Examiner concludes that it would have been obvious to one of ordinary skilled in the art at the time the invention was made to make Wright's, et al. second instrument sufficiently small to insert it within an incision of 1 to 2 mm as taught by Andrew.

It should be noted that Wright, et al. teaches the use of an instrument disclosed in U.S. 3,589,363 and 4,063,557, see column 3, line 60. These devices are sleeved ultrasonic needles.

More importantly, the Examiner acknowledges that the second instrument of Wright, et al. is a sleeveless aspirator. However, this aspirator is not ultrasonically vibrated as is claimed in the present application.

The present application is distinguished in that an unvibrated irrigation shaft is provided with a tool tip and a separate unsleeved ultrasonically vibrated needle is provided for emulsifying the cataract, see newly added claim 32.

This is totally contrary to the teachings of Wright, et al.

There is simply no suggestion or teaching in the combination of the Wright, et al. reference and the Andrew, et al. references of an unsleeved vibrated ultrasonic needle utilized for aspiration fluid from an eye capsule. As pointed out in the specification, this unique arrangement enables the ultrasonic needle to be inserted into a small wound without causing heating or damaged to the wound entry point.

Structure provided by the prior art teaches the use of a sleeved needle in order to prevent overheating of wound tissue. Such is the case with all the references cited by the Examiner.

While Andrew, et al. teaches the removal of lens nucleus from 1 to 2 mm corneal or limbal incision, the structure functions in the manner liquefying lens tissue without the use of ultrasound. Accordingly, the combination with Wright, et al. is improper.

The Applicants submit that there must be some logical reason apparent from positive, concrete evidence of record that justifies the combination of primary and secondary references. The mere fact that disclosures or references can be combined does not make the combination obvious, unless they are also suggest the desirability of the combination; in fact, there must be some motivation, or incentive, in order to combine the references. In Re Regel, Buchel and Plempel, 188 USPQ 136,139 (CCPA 1975); Berghauser, et al. v. Dann, 204 USPQ 393, 396 (Dist. Ct. Dist. Columbia 1978); A.C.H. Hospital Systems, Inc. v.

Montefiore Hospital, et al., 221 USPQ 929, 933 (Fed. Cir. 1984); and In Re Imperator, 179 USPQ 730, 732 (CCPA 1973).

In the case at hand, it is submitted that there is no incentive upon motivation for combining the liquefaction device of Andrew, et al. utilizing a small entry wound for an elongated cannula with a phacoemulsification device taught by Wright, et al.

Therefore, not only is the combination improper, but when combined there is still insufficient teaching to provide a prima facie case of obviousness of claims 3, 4, 26-28 and 31 under 35 USC 103(c). Accordingly, the Examiner is respectfully requested to withdraw the rejection of these claims on the basis of the Andrew, et al. and Wright, et al. references.

Claim 5 has been rejected by the Examiner under 35 USC 103(c) as being unpatentable over Wright, et al. in view of Andrew, et al. and further in view of U.S. 5,562,640 to McCabe, et al. The Examiner acknowledges that Wright and Andrew fail to disclose the first instrument comprising a plurality of irrigation ports and accordingly looks to McCabe for a teaching of a plurality of irrigation ports.

However, McCabe, does not add anything to deficiency of the Wright, et al. and Andrew, et al. references as hereinabove argued. Accordingly, a prima facie case of obviousness is not established with regard to claim 5 by the joining of the Wright, et al., Andrew, et al. and McCabe, et al. references. Withdrawal of this rejection is respectfully requested.

Claims 10, 11 and 29 have been rejected by the Examiner under 35 USC 103(c) as being unpatentable over Wright, et al. in view of Andrew, et al. and further in view of U.S. 6,013,049 to Rockley, et al. In this rejection, the Examiner states that while Wright discloses the use of an ultrasonic vibrating instrument, the instrument is associated with the irrigating instrument and not the aspirating instrument.

Accordingly, the Examiner looks to Rockley for a teaching of an ultrasonic aspirating instrument to emulsify the lens and concludes it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Wright device to give the aspirating device ultrasonic capabilities as taught by Rockley. In addition, the Examiner acknowledges that Wright fails to disclose a transverse tip and accordingly looks to Imonti for a teaching of a transverse tip.

While Rockley, et al. teaches the use of an ultrasonic needle with concomitant aspiration of fluid, the needle, like all of the references cited by the Examiner, is sleeved.

As specifically taught and claimed, the phacoemulsification handpiece for Rockley, et al. includes sleeved means, surrounding the needle means for causing outflow of irrigation from an eye in order to cool the needle means and maintaining the ocular pressure.

This is exactly the opposite of the structure taught in the present invention which includes a phacoemulsification needle which has no sleeve. Accordingly, this teaching of Rockley, et al. adds nothing to the deficiencies of the combination proposed by the Examiner and, as such, a prima facie case of obviousness has not been made with regard to claims 10, 11, 12 on the basis of 35 USC 103(c).

Claims 12, 17-25, 29 and 30 have been rejected by the Examiner under 35 USC 103(c) as being unpatentable over Wright, et al. in view of Andrew, et al., in view of Rockley, et al. and further in view of McCabe, et al. In this rejection, the Examiner stated that Wright, Andrew and Rockley meets some of the limitations of claims 12, 17-19, 29 and 30 but failed to disclose "a coupling medium for removably coupling each of the plurality of tool tips to the shaft". Nevertheless, the Examiner states that McCabe teaches in Figures 12a-14b a series of interchangeable tool tips attached to an irrigation and aspiration surgical tool use to manipulate tissue and includes it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Wright device as taught by McCabe to include a coupling medium with interchangeable tips.

However, none of this structure satisfies the basic deficiency of all of the references cited by the Examiner taken singly or in combination to suggest the unsleeved needle ultrasonic aspirator as presently claimed.

Accordingly, the Applicants submit that a prima facie case of obviousness has not been made with regard to claims 12, 17-25, 29 and 30 on the basis of 35 USC 103(c). Withdrawal of the rejection of these claims is respectfully requested.

In view of the arguments hereinabove set forth and amendment to the claims, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectively requested.

Respectfully submitted,



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